

REMARKS/ARGUMENTS

Applicants have carefully reviewed the Final Office Action mailed on June 19, 2009, and the Advisory Action mailed on September 15, 2009, prior to preparing this response. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. Claims 1-4, 6-34, 43, 73-78, and 82-96 remain pending and have been rejected. Claims 1, 14 and 43 have been amended with this paper. Support for the amendments may be found, for example, at paragraphs 0046 and 0050, of the Specification. No new matter has been added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claim Rejections under 35 U.S.C §103

Claims 1-4, 6-18, 20-29, 31, 33, 34, 43, 73-78, 82-84, and 88-96 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel et al. (U.S. Patent No. 6,942,680) in view of Vigil et al. (U.S. Patent No. 5,336,234) and Campbell et al. (U.S. Patent No. 5,458,572).

Claims 30 and 85-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel et al. (U.S. Patent No. 6,942,680) in view of Vigil et al. (U.S. Patent No. 5,336,234) and Campbell et al. (U.S. Patent No. 5,458,572) as applied to claims 1, 14, and 43 above, and further in view of Roychowdhury (U.S. Patent No. 5,587,125).

Claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Grayzel et al. (U.S. Patent No. 6,942,680) in view of Vigil et al. (U.S. Patent No. 5,336,234) and Campbell et al. (U.S. Patent No. 5,458,572) as applied to claim 14 above, and further in view of Spears (U.S. Patent No. 5,082,841). These rejections are respectfully traversed.

In response to Applicants previously presented remarks, it was stated in the Advisory Action that "There is no claim language preventing the stiffening member from being segmented in the manner expressed in the final rejection. When the stiffening member is segmented, it would NOT retain the folding configuration as disclosed in Campbell et al. because the areas between the segments would allow the balloon to completely collapse."

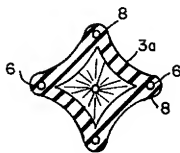
Applicants respectfully note that claim 1 has been amended with this response to recite a discrete strip of a second material encapsulated by the first material which extends

continuously along the body portion of the balloon into the first tapered portion and into the second tapered portion. Claim 14, as amended, recites that the discrete striped portion extends continuously along the body portion of the balloon, at least a portion of the first tapered portion, and at least a portion of the second tapered portion. Claim 43, as amended, recites that the discrete striped portion extends continuously from a first end of the tube to a second end of the tube. Thus, the claimed discrete strip or striped portion is not segmented. Furthermore, as currently claimed, portions of the inflatable balloon formed of the first material that are adjacent to the discrete strip form flaps between a furrow when the balloon is deflated such that the cutting element is located in the furrow between flaps of the inflatable balloon.

Applicants submit that the combination of references used in formulating the rejection is improper at least because the references themselves teach away from their combination in a manner as currently claimed. Specifically, the proposition in the Advisory Action speculating on the performance of a balloon with a segmented stiffening member embedded in the wall of the balloon has been obviated in view of the amendments to claims 1, 14 and 43.

Namely, in view of the teachings of Campbell et al. describing the effects of the discrete stripes (plastic material located within the lumens) which are more stiff than the balloon material, Campbell indicates that the balloon will form a shape depicted by Figure 2B when the balloon is collapsed. As seen in Figure 2B and discussed in column 3, line 65 to column 4, line 4, Campbell et al. teach that when the ribs or stiffening members (or the claimed discrete strips of a second material) have a higher stiffness than the balloon material (as is claimed), that the web of balloon material between the ribs will collapse inward when the balloon is deflated, leaving the ribs at the outermost portion of the collapsed balloon.

FIG. 2B is reproduced below.

**FIG.2B**

In this configuration, if cutting elements were centered over the stripes as claimed, the cutting elements would be on the outermost part of the balloon, and not disposed within the furrows as specified by Vigil et al.¹ Such a modification, as proposed in formulating the rejection, would run contrary to the express teachings of Vigil et al. Namely, this proposed modification would place the cutting elements in a location to produce significant damage to the blood vessel walls, a situation that would not be beneficial for the patient. Thus the combination asserted to be disclosed by the Examiner cannot be obtained from the cited references. Without the benefit of the Applicants' own application as a roadmap, one of ordinary skill in the art would not arrive at the claimed invention from the teachings of the cited references as the cited references teach away from the proposed modification.

There is no teaching in the cited prior art that a balloon having a continuously extending discrete strip or stripe of a second, stiffer material encapsulated therein would fold in a manner different from that taught in Campbell et al.

Since the Examiner relies upon Vigil et al. and Campbell et al. to provide elements missing from Grayzel et al., and it is clearly evident that these references cannot be combined in a way that will produce the claimed invention, Applicants submit that the cited combination is inadequate to create a *prima facie* case of obviousness. Applicants submit that Grayzel et al., Vigil et al., and Campbell et al. do not disclose all elements of independent claims 1, 14, and 43, and cannot be properly combined to arrive at the claims. Therefore, claims 1, 14, and

¹ Vigil et al. teach that when atherotomes (cutting blades) are present on the outside of a balloon, it is desirable to surround the blades with balloon material when the balloon is deflated so as to protect the vessel walls from contact with, and thus damage from, the blade edges. See Vigil et al. at column 4, lines 9-13 and Figure 2.

43 are believed to be patentable over the cited references. Accordingly, claims 2-4, 6-13, 15-18, 20-34, 73-78, and 82-96, which depend from claims 1, 14, or 43 and add additional elements thereto, are also believed to be nonobvious in view of the cited references. Withdrawal of the rejections is respectfully requested.

Conclusion

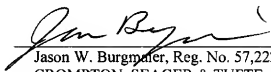
Further examination and withdrawal of the rejections are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their attorney,

Date: Oct 19, 2009



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